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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/683,535	10/10/2003	Judy Dering	58027-014000	2614

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EXAMINER

SIMS, JASON M

ART UNIT PAPER NUMBER

1631

DATE MAILED: 08/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/683,535

Applicant(s)

DERING ET AL.

Examiner

Jason M. Sims

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 08 June 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 2,4-7,9 and 12-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3,8,10 and 11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 10/10/03, 10/5/04
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Applicant's election of group I, claims 1-11, and election of the species expression data from mammals in the reply filed on 6/08/2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 2, 4-7, 9, and 12-14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventive group, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 6/08/2006.

Currently claims 1, 3, 8, and 10-11 are the current claim set hereby under examination.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1, 3, 8, and 10-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim1, line 4, the term "working" has been deemed vague and indefinite. It is unclear as to what the term "working" refers.

In claim1, line 6, the term "tissue samples" has been deemed vague and indefinite. It is unclear if applicant is referring to actual tissue samples or to tissue sample expression data sets.

Claim 1 recites the limitation "said gene-expression data sets" in line 4. There is insufficient antecedent basis for this limitation in the claim. Are there differences between expression data sets and working expression data sets?

Claim 1 recites the limitation "said tissue samples *of* said expression data sets" in line 6. There is insufficient antecedent basis for this limitation in the claim.

Claim 1 recites the limitation "said working gene set" in line 8. There is insufficient antecedent basis for this limitation in the claim.

Claims 3, 8, and 10-11 are rejected as being dependent from a rejected claim.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1, 3, 8, and 10-11 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Under the Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility (published in the O.G. notice (1300 OG 142) on 11/22/2005) a method that does not result in a physical transformation of matter MAY be statutory where it recites a concrete, tangible and useful result; i.e. a practical application.

In the instant case, the claims are directed to a constraint-based method for identifying a genomic target of interest from gene expression. In the instant case, the method of claims 1, 3, 8,

and 10-11 do not result in a physical transformation of matter, nor is any concrete, tangible and useful result produced/recited. Therefore, these claims are not statutory.

***Claim Rejections - 35 USC § 102***

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 3, and 10-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Roche et al. (US P/N 7, 062, 384).

The claims are directed to a constraint-based method for identifying a genomic target of interest from gene expression comprising of obtaining expression data sets from mammals and analyzing the co-expressions of members of the data sets and working gene sets to identify potential gene targets.

Roche et al. teaches claims 1 and 3 at col. 1, lines 25-33 and lines 50-67, col. 2, lines 1-26, col. 3, lines 5-25, col. 4, lines 47-67, and col. 5, lines 1-17. At col. 1, lines 215-33, Roche et al. discusses using gene expression data for prediction and classification, which represents identifying targets of interest using gene expression profiles. At col. 1, lines 51-58, Roche et al. discusses using gene expression data from

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microarrays from human cancer research, which represents obtaining tissue sample expression data sets from mammals.

At col. 1, lines 50-67 and col. 2, lines 1-26, Rocke et al. discusses using gene expression profiles from particular tissues such as breast cancer, which represents selecting a working gene-expression data set having a plurality of members. Additionally, Rocke et al. discusses distinguishing between negative and positive BRCA1 and BRCA2 mutations, which represents defining subgroups, in this case negative and positive groups, and analyzing the co-expression of the members of the working gene sets to identify potential gene targets, in this case the BRCA1 and BRCA2 genes. Rocke et al. also discusses using a weighted voting scheme for classification of acute leukemia based on gene expression data, which represents defining subgroups based on a constrained definition.

At col. 3, lines 5-25, Rocke et al. discusses obtaining biological sample data, which represents tissue sample expression data. Rocke et al. also discusses using a dimension reduction data step to reduce the expression data, which represents using a constrained definition to define subgroups. Additionally, Rocke et al. discusses using the reduced data, or subgroups, to generate a model useful for predicting the classification of a biological sample, which represents analyzing co-expression data of members of gene sets in the subgroup to identify potential gene targets.

At col. 4, lines 47-67 and col. 5, lines 1-17, Rocke et al. discusses using gene expression data sets such as a breast cancer data set with a BRCA1 or BRCA2 mutation, for multivariate classification, which represents analyzing co-expression data

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from subgroups to identify potential gene targets, in this case the potential gene targets are BRCA1 or BRCA2 mutations.

Rocke et al. teaches claim 10 at col. 24, lines 15-34. Rocke et al. discusses studying gene expression patterns where breast cancer cases are attributed to BRCA1 or BRCA2 gene mutations, which represents selecting known prognostic markers, in this case particular mutations, that are correlated with prognostic outcomes, in this case breast cancer.

Rocke et al. teaches claim 11 at col. 5, lines 65-67 and col. 6, lines 1-10. Rocke et al. describes a method of data reduction and classification, which represents a method or step of binning working gene-expression sets.

### ***Conclusion***

#### ***No claims Allowed***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason Sims, whose telephone number is (571)-272-7540.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Andrew Wang can be reached via telephone (571)-272-0811.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (571)-273-8300.

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Any inquire of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Yolanda Chadwick, whose telephone number is (571)-272-0514.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*Carly* *SV*  
8/7/06 AV 1631 examiner